DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 9, 2014

Shenzhen Pump Medical System Co., Ltd.
c/o Ms. Xie Qiongyu
Deputy General Manager
2/f West, M-7 Sinosteel Building, Maqueling Estate
Hi-tech Industrial Park
Nanshan District, Shenzhen, Guangdong, 518057 CN

Re: K141416
Trade/Device Name: Blood Pressure Monitor, Model No. BF2200, BF2210, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207, BF2217
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: Not Dated
Received: August 11, 2014

Dear Ms. Xie Qiongyu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141416

Device Name: Blood pressure monitor

Indications for Use:

It is intended for measuring adult blood pressure and pulse rate with circumference ranging from 135 mm to 215 mm..

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use √ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

1. Applicant

Applicant Name: SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.

Address: 2/F West, M-7 Sinosteel Building, Maqueling Estate,
Hi-Tech Industrial Park, Nanshan District,
Shenzhen 518057, China

Contact person:

Name: Xie Qiongyu

Phone numbers: 86-0755-26710795

Fax numbers: 86-0755-26012025

E-mail: xieqy@bpump.com.cn

Date Prepared: 2014-3-30

2. Device information

- **Trade name:** Blood pressure monitor
- **Model No.:** BF2200, BF2210, BF2201, BF2211, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207 and BF2217
- **Regulation Description:** Noninvasive blood pressure measurement system.
- **Regulation Number: 21CFR 870.1130**
- **Product Code: DXN**
- **Class: II**
- **Review Panel:** Cardiovascular
- **Indications for Use:** It is intended for measuring adult blood pressure and pulse rate with circumference ranging from 135 mm to 215 mm.

3. Predicate Devices

- **Noninvasive blood pressure measurement system**

- **K-number:** K123498
- **Product Code:** DXN
- **Intended User:**
  Home user
- **Patient Population:**
  This device is intended for use on adults.
- I**ndications for Use:**
  The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).

  The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
- **Manufactured by**
  Omron Healthcare, Inc.

4. Description of the device

Blood pressure monitor is based on pressure vibration method. Blood pressure cuff use the air pump to inflate, then the arteries are extruded by the cuff with pressure. Pressure sensor collects the pressure in the cuff, and then converts it to digital signal to the CPU. Then the software calculates the systolic and diastolic blood pressure and pulse rate.

The blood pressure monitor BF2200, BF2210, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207 and BF2217 have the same basic principles, main function, performance and intended use, and they are consistent in product structure and material.

5. Testing data and clinical study

Laboratory testing was conducted to validate and verify that Blood pressure monitor met all requirements of related international standards, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of the bellow consensus standards. Clinical study has been evaluated according to ANSI/AAMI SP10 and ANSI/AAMI/ISO 81060-2.

Applied Standard:
Electrical Safety and performance requirements: IEC 60601-1 AAMI performance standard ANSI/AAMI SP10 EN 81060-2-30
Home-used medical equipment requirements and Environmental test: IEC 60601-1-11
Electromagnetic Compatibility Requirements: EN 60601-1-2
Biocompatibility Evaluation for NIBP Cuff ISO 10993-1, ISO 10993-5, ISO 10993-10
Clinical Evaluation: ANSI/AAMI SP10 ANSI/AAMI/ISO 81060-2

Conclusion:

According to above information, comparing to the predicate, the subject devices do not constitute a new intended use, and used same the Measuring Principle, same electrical noninvasive blood pressure measurement technologic and same measurement site (measuring on wrist).

The subject devices have been evaluated to meet IEC 60601-1, IEC 60601-12, AAMI/ANSI SP10, EN 80601-2-30, ISO 10993-5, and ISO 10993-10. The related test reports and clinical study reports demonstrate and do not raise different questions of safety and effectiveness than the predicate.

As a result, the subject device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device.

6. Comparison to Predicate Devices

Parameter	**Name: Blood Pressure Monitor** **Model No.:** **BF2200, BF2210, BF2201, BF2211, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207 and BF2217**	**Name: Noninvasive Blood Pressure Measurement System (K123498)** **Model No.: BP652N (HEM-6300-Z)**
Intended use	Measurement of human blood pressure and pulse rate for adults.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1⁄4 inches to 8 1⁄2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
Patient Population	Adult	Adult
Environment of Use	Home	Home
Technology	Oscillometric method	Oscillometric method
Anatomical sites	Wrist	Wrist
Measurement range	Blood pressure: 0mmHg～280mmHg (0kPa～37.3kPa)	Blood pressure: 0mmHg～299mmHg (0kPa～39.9kPa)
	Pluse: 40 pulse/min ～180 pulse/min	Pluse: 40 pulse/min ～180 pulse/min
Measurement accuracy	Static pressure: ±3mmHg(±0.4kPa)	Static pressure: ±3mmHg(±0.4kPa)
	Pluse: ±5%	Pluse: ±5%

Parameter	**Name: Blood Pressure Monitor** **Model No.:** **BF2200, BF2210, BF2201, BF2211, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207 and BF2217**	**Name: Noninvasive Blood Pressure Measurement System (K123498)** **Model No.: BP652N (HEM-6300-Z)**
Display	LCD	LCD
Power source	2AAA Alkaline batteries	2AAA Alkaline batteries
Operating environment	Temperature: +5℃～+40℃	Temperature: +10℃～+40℃
	Humidity: ≤93%	Humidity: 15%～85%
Storage environment	Temperature: -25℃～+70℃	Temperature: -20℃~+60℃
	Humidity: 10%～95%	Humidity: 10%～95%

The subject device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device.

7. Conclusion

As stated above, the Blood pressure monitors (Models: BF2200, BF2210, BF2201, BF2211, BF2202, BF2212, BF2203, BF2213, BF2204, BF2214, BF2205, BF2215, BF2206, BF2216, BF2207 and BF2217) are safe and effective, and comply with the appropriate medical device standards. And they are substantially equivalent to the earlier identified predicate devices.